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(54) Manufacturing vascular prostheses by electrostatic spinning

(57) Apparatus for manufacturing synthetic vascular grafts by an electrostatic spinning process comprises a rotating mandrel (10), an array of capillary needles (11,12,13) arranged on a manifold (14) for directing polymer solution towards the mandrel (10) when electrostatically charged, and electrodes (18,19) for influencing the electrostatic field experienced by the polymer solution. There are means for altering the electrostatic charge of the electrodes (18,19).

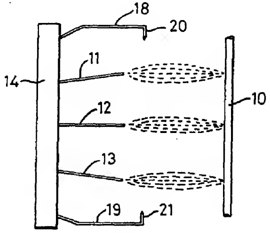

FIG. 2

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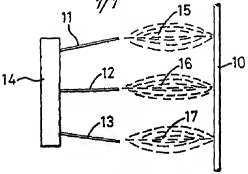

FIG. 1

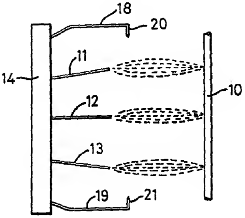

FIG. 2

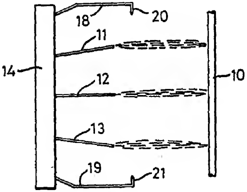

FIG. 3

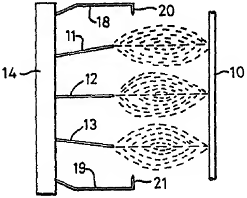

FIG. 4

SPECIFICATION

Improvements in synthetic vascular grafts and methods and apparatus for manufacturing such grafts

The invention relates to synthetic vascular grafts and their manufacture.

It has been proposed to make synthetic vascular grafts by an electrostatic spinning technique, as described for example in Published European Application No. 0005035. It has also been appreciated that anisotropic variations of synthetic vascular grafts constructions can assist in matching the physical properties of the graft to the physical properties of a natural artery. In our copending application No. 8216066, a method of varying anisotrophic properties of a synthetic vascular graft by varying the rotational speed of the mandrel in the electrostatic spinning process is described.

According to the invention there is provided apparatus for electrostatically spinning synthetic vascular grafts comprising a mandrel, means for rotating the madrel, means for electrostatically charging the mandrel, means for directing organic polymeric material towards the mandrel, and electrode means located in the region of the material directing means for influencing the electrostatic field caused by electrostatic charging of the mandrel, in use.

The electrode means may comprise a pair of electrode arranged one each side of the material directing means.

The material directing means may comprise at least one and preferably an array of capillary needles.

The apparatus preferably further comprises means for controlling the electrostatic potential of the electrode means.

The mandrel may be of uniform diameter, or may taper.

The apparatus may comprise means for varying the speed of rotation of the mandrel, and means for varying the rotational speed of the mandrel in accordance with the traverse position of the fluid directing means.

The invention further provides a method of manufacturing a synthetic vascular graft by electrostatically spinning an organic polymeric material or a precursor thereof and collecting the spun fibres on an electrostatically charged mandrel, which method comprises the step of influencing the electrostatic field caused by electrostatic charging of the mandrel by electrode means located in the region of means for directing the organic polymeric material towards the mandrel, to achieve a desired degree of anistrophy in the synthetic vascular graft.

The electrode means may be at zero, positive or negative potential with respect to the material directing means.

The method may also comprise the step of controlling the speed of rotation of the mandrel. The mandrel speed may be kept at a uniform level during production of an individual graft or may be varied.

The invention further provides a synthetic vascular graft made by apparatus or a method according to the invention.

By way of an example, one embodiment according to the invention of apparatus for and method of making synthetic vascular grafts, will now be described with reference to the accompanying drawings, in which:–

Figure 1 is a diagrammatic illustration of a known apparatus for electrostatically spinning a synthetic vascular graft;

Figure 2 is a diagrammatic illustration of an embodiment of apparatus according to the invention in which electrodes are present in the region of needles for solution ejection, the electrodes being at the same potential as tha needles;

Figure 3 is a diagrammatic illustration of the apparatus of Fig. 2 with the electrodes at positive potential with respect to the needles; and

Figure 4 is a diagrammatic illustration of the apparatus of Figs. 2 and 3 with the electrodes at negative potential with respect to the needles.

As shown in Fig. 1, a known embodiment of electrostatic spinning apparatus comprises a rotating mandrel 10 and an array of stainless steel capillary needles, 11, 12 and 13 mounted on a manifold 14. The manifold 14 is traversed along the length of the mandrel and a solution of polymeric material, such as polyurethane is ejected from the needles. The mandrel 10 is rotated at a desired speed, normally in the range to 25000 rpm and preferably between 2000 and 20000 rpm. The mandrel is maintained at a potential, normally -12 kv, with respect to the needles 11, 12, 13 such that an electrostatic field is created. When a droplet of polyurethane leaves a needle and enters the electrostatic field, the droplet elongates to form a cone or jet and from the end of the jet, fine fibres of diameter in the range of 1 to 2 μm are are produced and attracted to the mandrel 10. Fig. 1 illustrates the shape of flows 15, 16 and 17 from the needles 11, 12 and 13 respectively. It has been found that variation of mandrel rotation speed causes variation in anisotriophy of the graft produced, for a 10mm internal

diameter graft, with values of the ratio of circumferential Young's modulus (E_θ) to longitudinal Young's modulus (E_z) varying from approximately 0.6 for a rotational speed of 2000 rpm to approximately 1.3 for a rotational speed of 9000 rpm.

Figs. 2, 3 and 4 show the apparatus of Fig. 1 with, in addition, electrodes 18 and 19 arranged at each end of the array of needles 11, 12, 13. The electrodes 18 and 19 are in the form of plates having inwardly turned end portions 20 and 21 respectively, although it will be appreciated that other forms could be used.

Fig. 2 shows the effect of the presence of the electrodes 18 and 19 in flow of polymer when there is no potential difference between the electrodes and the needles. In Fig. 3, the electrodes are at a positive potential with respect to the needles, and in Fig. 4, the electrodes are at a negative potential with respect to the needles.

As can be seen from Fig. 2, the presence of the electrodes 18 and 19 focusses the electrostatic field acting in the solution of polymer to draw in the flow. This effect is accentuated when a positive potential is applied to the electrodes, but when a negative potential is applied to the electrodes, the attraction of the mandrel in the region of the needles is reduced and the material flow is correspondingly divergent.

Tests carried out in synthetic vascular grafts produced with the electrodes 18 and 19 at the potential of the needles 11, 12 and 13 and compared with tests on synthetic vascular grafts made under similar conditions but without the electrodes 18 and 19 being present, indicate that:

(a) the electrodes 18 and 19 cause an increase in the average initial elastic modulus of 80%

(b) an increase in the ratio of initial elastic modulus in the circumferential direction to the axial direction (E_θ:E_z) of 60%.

By varying the potential of the electrodes 18 and 19, variations in the anisotropy of the synthetic vascular graft can be achieved. This provides an advantage over the method disclosed in our application No. 8216066 in which anisotropy variations were achieved by varying the mandrel rotation speed, as a limit on the maximum rotation speed of the mandrel and minimum graft diameter imposed restrictions on the degree of anisotropy which could be obtained.

EXAMPLE

All experiments were performed as previously described, but in particular:
1) polyurethane solution was 12.5% w/w.
2) mandrel rotation was 1500 rpm.
3) mandrel diameter was 3/8".
4) solution flow rate was 6.5 ml/hr.
5) 3 needles were used.

Expt.	E_z	E_θ	Average E	Ratio E_z:E_θ
No auxilliary electrodes	3.43	2.56	3.00	1.34
Auxilliary electrodes at 0v wrt needles	4.49	4.02	4.26	1.12
Auxilliary electrodes at -1Kv wrt needles	2.91	1.9	2.41	1.21
Auxilliary electrodes at +400V wrt needles	5.13	5.45	5.26	0.94

CLAIMS

1. Apparatus for electrostatically spinning synthetic vescular grafts comprising a mandrel, means for rotating the mandrel, means for electrostatically charging the mandrel, means for

directing organic polymeric material towards the mandrel, and electrode means located in the region of the material directing means for influencing the electrostatic field caused by electrostatic charging of the mandrel, in use.

2. Apparatus as claimed in claim 1, wherein the electrode means comprise a pair of electrodes arranged one each side of the material directing means.

3. Apparatus as claimed in claim 1 or claim 2 comprising means for controlling the electrostatic potential of the electrode means.

4. Apparatus as claimed in claim 1, claim 2 or claim 3, wherein the material directing means comprise at least one capillary needle.

5. Apparatus as claimed in claim 4, wherein the material directing means comprise an array of capillary needles.

6. Apparatus as claimed in any preceding claim comprising means for varying the speed of rotation of the mandrel.

7. Apparatus as claimed in claim 6 comprising means for varying the rotational speed of the mandrel in accordance with the transverse position of the material directing means.

8. Apparatus as claimed in any preceding claim, wherein the mandrel is of unform diameter.

9. Apparatus as claimed in any one of claims 1 to 7, wherein the mandrel tapers.

10. A method of manufacturing a synthetic vascular graft by electrostatically spinning an organic polymeric material or a precursor thereof and collecting the spun fibres of an electrostatically charged mandrel, which method comprises the step of influencing the electrostatic field caused by electrostatic charging of the mandrel by electrode means located in the region of means for directing the organic polymeric material towards the mandrel, to achieve a desired degree of anisotropy in the synthetic vascular graft.

11. A method as claimed in claim 10 comprising the step of controlling the speed of rotation of the mandrel.

12. A method as claimed in claim 10, wherein the mandrel speed is kept at a uniform level during production of an individual graft.

13. A method as claimed in any one of claims 10 to 12, wherein the electrode means are at the same potential as the material directing means.

14. A method as claimed in any one of claims 10 to 12, wherein the electrode means are at a negative potential with respect to the material directing means.

15. A method as claimed in any one of claims 10 to 12, wherein the electrode means are at a positive potential with respect to the material directing means.

16. Apparatus for electrostatically spinning synthetic vascular grafts substantially as hereinbefore described with reference to and as shown in Figs. 2, 3 and 4 of the accompanying drawings.

17. A method of manufacturing a synthetic vascular graft substantially as hereinbefore described with reference to and as shown in Figs. 2, 3, or 4 of the accompanying drawings.

18. A synthetic vascular graft made by apparatus as claimed in any one of claims 1 to 9 and 16.

19. A synthetic vascular graft made by a method as claimed in any one of claims 10 to 15 and 17.

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